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# FULBRIGHT & JAWORSKI L.L.P.

A REGISTERED LIMITED LIABILITY PARTNERSHIP

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Commissioner for Patents  
Washington, DC 20231

RE: SN 09/974,546 "BIOMARKERS AND TARGETS FOR DIAGNOSIS, PROGNOSIS AND MANAGEMENT OF PROSTATE, BREAST AND BLADDER CANCER" — Gang An, et al.

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement and Form PTO-1449.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10109245/GNS.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Gina N. Shishima  
Reg. No. 45,104

GNS/cas

Encl: as noted

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Gang An et al.

Serial No.: 09/974,546

Filed: October 10, 2001

For: BIOMARKERS AND TARGETS FOR  
DIAGNOSIS, PROGNOSIS AND  
MANAGEMENT OF PROSTATE,  
BREAST AND BLADDER CANCER



Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: UROC:018USD2/GNS

*K.T.*  
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*F.D.S.*

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10109245/GNS.

This application is a divisional application of Serial No. 09/097,199, filed June 12, 1998, and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 09/097,199.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Reg. No. 45,104  
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**INFORMATION DISCLOSURE STATEMENT**

(Use several sheets if necessary)

Applicants

David Ralph, Gang An, Mark O'Hara and Robert Veltri

Filing Date:  
October 10, 2001Group:  
UnknownU.S. Patent Documents  
See Page 1Foreign Patent Documents  
See Page 1Other Art  
See Page 1**U.S. Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date if App.
	A1	5,262,311	11/16/93	Pardee <i>et al.</i>	435	91.2; 6	
	A2	5,633,161	05/27/97	Shyjan	435	325	
	A3	5,639,656	06/17/97	Wright, Jr.	435	344.1	
	A4	5,665,547	09/09/97	Pardee <i>et al.</i>	435	6	
	A5	5,342,762	08/30/94	Mosher <i>et al.</i>	435	69.1	
	A6	5,455,158	10/03/95	Vogel <i>et al.</i>	435	7.21	
	A7	5,487,985	01/30/96	McClelland <i>et al.</i>	435	91.2	
	A8	5,550,214	08/27/96	Eberlain <i>et al.</i>	530	328	

**Foreign Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 94/10343	05-11-94	PCT	C12Q	1/68	

**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

Exam. Init.	Ref. Des.	Citation
	C1	Alcaraz <i>et al.</i> , "Aneuploidy and aneusomy of chromosome 7 detected by fluorescence <i>in situ</i> hybridization are markers of poor prognosis in prostate cancer", <i>Cancer Res.</i> , 54:3998-4002, 1994.
	C2	An <i>et al.</i> , "Isolation of Genes differentially expressed in prostate cancer cells with metastatic potential by arbitrarily-primed differential analyses (ADA)," <i>Proc. Amer. Assn. Canc. Res.</i> , 36:82(491), 1995.
	C3	Bookstein <i>et al.</i> , "Suppression of tumorigenicity of human prostate carcinoma cells by replacing a mutated RB gene," <i>Science</i> , 247:712-715, 1990.

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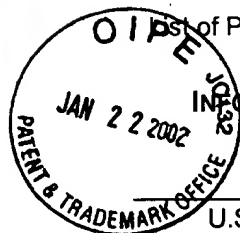
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List of Patents and Publications for Applicant's

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Exam. Init.	Ref. Des.	Citation
	C4	Bookstein <i>et al.</i> , "Promoter deletion and loss of retinoblastoma gene expression in human prostate carcinoma," <i>Proc. Natl. Acad. Sci. USA</i> , 87:7762-7766, 1990.
	C5	Bova <i>et al.</i> , "Homozygous deletion and frequent allelic loss of chromosome 8p22 loci in human prostate cancer," <i>Cancer Res.</i> , 53:3869-3873, 1993.
	C6	Carter <i>et al.</i> , "Allelic loss of chromosomes 16q and 10q in human prostate cancer," <i>Proc. Natl. Acad. Sci. USA</i> , 87:8751-8755, 1990.
	C7	Chen <i>et al.</i> , "Androgen-independent human prostate cancer progression: the isolation of novel stage-specific sequences using differential mRNA display," <i>Proc. Natl. Urol. Assn.</i> , 153:267A, 1995.
	C8	Donohue <i>et al.</i> , "A delayed-early gene activated by fibroblast growth factor-1 encodes a protein related to aldose reductase", <i>J. Biol. Chem.</i> , 269(11):8604-8609, 1994.
	C9	Dumont <i>et al.</i> , "Relationship between multiple biologic effects of rapamycin and the inhibition of pp70S6 protein kinase activity," <i>J. Immunology</i> , 992-1003, 1994.
	C10	Isaacs <i>et al.</i> , "Molecular biology of prostate cancer," <i>Seminars in Oncology</i> , 21(5):514-521, 1994.
	C11	Isaacs <i>et al.</i> , "Wild-type p53 suppresses growth of human prostate cancer cells containing mutant p53 Alleles," <i>Cancer Res.</i> , 51:4716-4720, 1991.
	C12	Liang, Peng, Pardee, "Differential display of eukaryotic messenger RNA by means of the polymerase chain reaction", <i>Science</i> , 257:967-971, 1992.
	C13	Liang <i>et al.</i> , "Differential display and cloning of messenger RNAs from human breast cancer versus mammary epithelial cells", <i>Cancer Res.</i> , 52:6966-6968, 1992.
	C14	Macoska <i>et al.</i> , "Fluorescence in Situ hybridization analysis of 8p allelic loss and chromosome 8 instability in human prostate cancer", <i>Cancer Research</i> , 54:3824-3830, 1994.
	C15	Mok <i>et al.</i> , "Molecular cloning of differentially expressed genes in human epithelial ovarian cancer", <i>Gynecological Oncology</i> , 52:247-252, 1994.
	C16	Morton <i>et al.</i> , "Multivariate analysis of the relationship between survival and the microstage of primary melanoma by clark level and breslow thickness," <i>Cancer</i> , 71(11):3737-3743, 1993.

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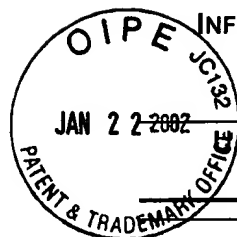
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Exam. Init.	Ref. Des.	Citation
	C17	Morton <i>et al.</i> , "Reduction of E-cadherin levels and deletion of the $\alpha$ -catenin gene in human prostate cancer cells," <i>Cancer Research</i> , 53:3585-3590, 1993.
	C18	Qiao <i>et al.</i> , "Effects of suramin on expression of proliferation associated nuclear antigens in DU-145 prostate carcinoma cells," <i>Biochemical and Biophysical Research Communications</i> , 201(2):581-588, 1994.
	C19	Riber, Manuel, Rieber, "Cyclin-dependent kinase 2 and cyclin A interaction with E2F are targets for tyrosine induction of B16 melanoma terminal differentiation," <i>Cell Growth and Differentiation</i> , 5:1339-1346, 1994.
	C20	Sager <i>et al.</i> , "Identification by differential display of alpha-6 integrin as a candidate tumor suppressor gene," <i>Methodology Communications</i> , 7:964-970, July, 1993.
	C21	Scott <i>et al.</i> , "A truncated intracellular HER2/neu receptor produced by alternative RNA processing affects growth of human carcinoma cells," <i>Molecular and Cellular Biology</i> , 13(4):2247-2257, 1993.
	C22	Slamon <i>et al.</i> , "Expression of cellular oncogenes in human malignancies," <i>Science</i> , 224:256-262, 1984.
	C23	Takahashi <i>et al.</i> , "Potential markers of prostate cancer aggressiveness detected by fluorescence <i>in Situ</i> hybridization in needle biopsies," <i>Cancer Research</i> , 54:3574-3579, 1994.
	C24	Umbas <i>et al.</i> , "Expression of the cellular adhesion molecule E-cadherin is reduced or absent in high-grade prostate cancer," <i>Cancer Research</i> , 52:5104-5109, 1992.
	C25	Visakorpi <i>et al.</i> , "Sensitive detection of chromosome copy number aberrations in prostate cancer by fluorescence <i>In Situ</i> hybridization," <i>J. Pathology</i> , 145(3):624-630, 1994.
	C26	Watson and Fleming, "Isolation of differentially expressed sequence tags from human breast cancer," <i>Cancer Research</i> , 54:4598-4602, 1994.
	C27	Webb and Lin, "Urinary fibronectin-potential as a biomarker in prostatic cancer," <i>Investigative Urology</i> , 17(5):401-404, 1980.
	C28	Welsh <i>et al.</i> , "Arbitrarily primed PCR fingerprinting of RNA," <i>Nucleic Acids Research</i> , 20(19):4965-4970, 1992.

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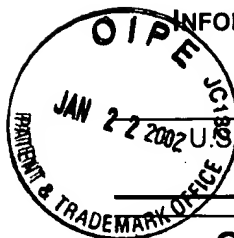
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	C29	Wong <i>et al.</i> , "Identification of differentially expressed RNA in human ovarian carcinoma cells by arbitrarily primed PCR fingerprinting of total RNAs," <i>Intl. J. Onc.</i> , 3:13-17, 1993.
	C30	An <i>et al.</i> , "Identification of novel gene markers in prostate disease by RNA fingerprinting," <i>Proc. American Assoc. Cancer Res. Annual Mtg</i> , Abstract No. 1692 37(0):248, 1996.
	C31	An <i>et al.</i> , "Sensitive, nonradioactive differential display method using chemiluminescent detection," <i>Biotechniques</i> , 20(3):342, 344, 346, 1996.
	C32	Blok <i>et al.</i> , "Isolation of cDNAs that are differentially expressed between androgen-dependent and androgen-independent prostate carcinoma cells using differential display PCR <sup>TM</sup> ," <i>Prostate</i> , 26(4):213-224, 1995.
	C33	Hamdy <i>et al.</i> , "Circulating prostate specific antigen-positive cells correlate with metastatic prostate cancer," <i>Brit. J. Urology</i> , 69(4):392-396, 1992.
	C34	Robson <i>et al.</i> , "Identification of prostatic androgen regulated genes using the differential display technique," <i>Proc. American Assoc. Cancer Research Annual Meeting</i> , Abstract No. 1589. 36:266, 1995.
	C35	EMBL. Sequence Data Library, Heidelberg, BRD, XP002019347, Accession no. W67972
	C36	PCT Search Report mailed March 7, 1997.
	C37	Adam and Wright Jr., "Identification of biomarkers in benign: prostate hyperplasia and prostate carcinoma by differential display," <i>Proceedings</i> , 86th Annual Meeting American Association for Cancer Research, March 1995.
	C38	Badalament <i>et al.</i> , "An algorithm for predicting nonorgan confined prostate cancer using the results obtained from sextant core biopsies with prostate specific antigen level," <i>J. Urol.</i> , 156:1375-1380, 1996.
	C39	Bussemakers <i>et al.</i> , "Identification of high mobility group protein I(Y) as potential progression marker for prostate cancer by differential hybridization analysis," <i>Cancer Res.</i> , 51:606-611, 1991.
	C40	Deguchi <i>et al.</i> , "Detection of micrometastatic prostate cancer cells in lymph nodes by reverse transcriptase-polymerase chain reaction," <i>Cancer Research</i> , 53:5350-5354, 1993.

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	C41	Garcia-Arenas <i>et al.</i> , "The expression of prostatic acid phosphatase in transcriptionally regulated in human prostate carcinoma cells," <i>Mol. Cell. Endocrin.</i> , 111:29-37, 1995.
	C42	Kawasaki and Wang, "Detection of gene expression," <i>In: PCR Technology</i> , Henry A. Erlich (ed.), Stockton Press, 1989.
	C43	O'Dowd <i>et al.</i> , "Update on the appropriate staging evaluation for newly diagnosed prostate cancer," <i>J. Urol.</i> , 158:687-698, 1997.
	C44	Orozco <i>et al.</i> , "Observations on pathology trends in 62,537 prostate biopsies obtained from urology private practices in the United States," <i>Urology</i> , 51(2):186-195, 1998.
	C45	Prashar <i>et al.</i> , "Analysis of differential gene expression by display of 3' end restriction fragments of cDNAs," <i>Proc. Natl. Acad. Sci. USA</i> , 93:569-663, 1996.
	C46	Veltri <i>et al.</i> , "Ability to predict biochemical progression using gleason score and a computer-generated quantitative nuclear grade derived from cancer cell nuclei," <i>Urology</i> , 48(5):685-691, 1996.
	C47	Wingo <i>et al.</i> , "An adjustment to the 1997 estimate for new prostate cancer cases," <i>CA-A Cancer Journal for Clinicians</i> , 47(4):239-242, 1997.
	C48	An <i>et al.</i> , "Differential expression of full-length and a truncated Her-2/ <i>neu</i> oncogene receptor in prostate cancer assessed using relative quantitative RT-PCR," <i>Molecular Urology</i> , 2(4):305-310, 1998.
	C49	Veltri <i>et al.</i> , "Interleukin-8 serum levels in patients with benign prostatic hyperplasia and prostate cancer," <i>Urology</i> , 53(1):139-147, 1999.
	C50	Veltri <i>et al.</i> , "The role of biopsy pathology, quantitative nuclear morphometry, and biomarkers in the preoperative prediction of prostate cancer staging and prognosis," <i>Seminars in Urologic Oncology</i> , 16(3):106-117, 1998.
	C51	Chen <i>et al.</i> , "Androgen-independent human prostate cancer progression: the isolation of novel stage-specific sequences using differential mRNA display," <i>J. Urol.</i> , 153(Supp. 4):267, Abstract 154, April 1995.
	C52	Adam <i>et al.</i> , "Identification of biomarkers in benign prostate hyperplasia and prostate carcinoma by differential display," <i>Proc. Amer. Assoc. Cancer Res.</i> , 36:25, Abstract 150, March 1995.

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